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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,258	12/21/2001	Carsten Schelp	05552.1450	5022

7590 07/14/2004

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Washington, DC 20005-3315

EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/024,258

Applicant(s)

SCHELP ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 and 27-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-18 and 23-26 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of Group 1, claims 1-18 and 23-26 with traverse of the paper mailed April 23, 2004 is acknowledged. The traversal is on the ground(s) that the restricted groups I and II are not independent and distinct one from the other, there is not considerable overlap between the two and there is not burden to search the two inventions. This argument is not found persuasive. MPEP 802.01 provides that restriction is proper between inventions which are independent or distinct. Here, the inventions of the various groups are distinct for the reasons set forth in the Paper mailed March 23, 2004. As to the question of burden of search, the inventions are classified differently, necessitating different searches in the US Patent shoes. Further, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search. Different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Upon reconsideration, it is found that Group 1 is further subject to restriction, see new restriction requirement below:

2. Claim 1 links inventions (1A-1I) and (AA)-(BB). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim

1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 1A. claims 1-4, 7-18 and 23-26 are drawn to a method of detecting analyte A wherein R2 is an analyte A specific binding partner which saturates analyte A-binding sites at a higher analyte A concentration than the analyte A specific binding partners, wherein L1- dependent measurement signal is determined at a different time from an L2 dependent measurement signal, classified in Class 435, subclasses 4, 7.1.

Group 1B. claims 1-4, 7-18 and 23-26 are drawn to a method of detecting analyte A wherein R2 is an analyte A specific binding partner which binds analyte A-binding sites at a time later than other analyte A specific binding partners, wherein L1- dependent

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measurement signal is determined at a different time from an L2 dependent measurement signal, classified in Class 435, subclasses 4, 7.1.

Group 1C. claims 1-4, 7-18 and 23-26 are drawn to a method of detecting analyte A wherein R2 is an analyte A specific binding partner which binds analyte A-binding sites at both a higher analyte A concentration and at a time later than other analyte A specific binding partners, wherein L1- dependent measurement signal is determined at a different time from an L2 dependent measurement signal, classified in Class 435, subclasses 4, 7.1.

Group 1D. claims 1-4, 7-18 and 23-26 are drawn to a method of detecting analyte A wherein R2 is an analyte A specific binding partner which saturates analyte A-binding sites at a higher analyte A concentration than othe analyte A specific binding partners, wherein L1 and L2 dependent measurement signals are determined at the same time, classified in Class 435, subclasses 4, 7.1.

Group 1E. claims 1-4, 7-18 and 23-26 are drawn to a method of detecting analyte A wherein R2 is an analyte A specific binding partner which binds analyte A-binding sites at a time later than other analyte A specific binding partners, wherein L1 and L2 dependent measurement signals are determined at the same time, classified in Class 435, subclasses 4, 7.1.

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Group 1F. claims 1-4, 7-18 and 23-26 are drawn to a method of detecting analyte A wherein R2 is an analyte A specific binding partner which binds analyte A-binding sites at both a higher analyte A concentration and at a time later than other analyte A specific binding partners, wherein L1 and L2 dependent measurement signals are determined at the same time, classified in Class 435, subclasses 4, 7.1.

Group 1G. claims 1-4, 7-18 and 23-26 are drawn to a method of detecting analyte A wherein R2 is an analyte A specific binding partner which saturates analyte A-binding sites at a higher analyte A concentration than the analyte A specific binding partners, wherein L1 dependent measurement is determined using a different measurement method than used to determine L2 dependent measurement signal, classified in Class 435, subclasses 4, 7.1.

Group 1H. claims 1-4, 7-18 and 23-26 are drawn to a method of detecting analyte A wherein R2 is an analyte A specific binding partner which binds analyte A-binding sites at a time later than other analyte A specific binding partners, wherein L1 dependent measurement is determined using a different measurement method than used to determine L2 dependent measurement signal, classified in Class 435, subclasses 4, 7.1.

Group 1I. claims 1-4, 7-18 and 23-26 are drawn to a method of detecting analyte A wherein R2 is an analyte A specific binding partner which binds analyte A-binding sites

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at both a higher analyte A concentration and at a time later than other analyte A specific binding partners, wherein L1 dependent measurement is determined using a different measurement method than used to determine L2 dependent measurement signal, classified in Class 435, subclasses 4, 7.1.

3. For each of the inventions (1A)-(1I) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions IA-II and one of (AA) or (BB). It is noted that this is not an election of species requirement in that each of the linked groups consists of one of inventions IA-II and (AA)-(BB).

Group (AA), claim 5, wherein the label L2 is directly conjugated to R3.

Group (BB), claim 6, wherein the label L2 is conjugated to a binding partner that binds to a moiety conjugated to R3.

4. The inventions are distinct, each from the other because of the following reasons: Inventions I-VI are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.



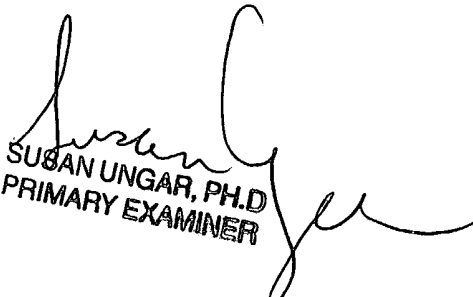
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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah A. Davis  
Remsen Bldg.  
Room 3D58  
July 12, 2004

  
SUSAN UNGAR, PH.D.  
PRIMARY EXAMINER